

Matthew Holian (Bar No. 211728)
matt.holian@dlapiper.com
DLA PIPER LLP (US)
33 Arch Street, 26th Floor
Boston, MA 02110-1447
Tel: 617.406.6000
Fax: 617.406.6100

Andrew J. Hoffman II (Bar No. 259507)
andrew.hoffman@dlapiper.com
DLA PIPER LLP (US)
2000 Avenue of the Stars, Suite 400 North Tower
Los Angeles, CA 90067-4704
Tel: 310.595.3000
Fax: 310.595.3300

Attorneys for Adamas Defendants
[Additional Counsel on the Signature Page]

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

UNITED STATES OF AMERICA;
STATES OF CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE,
FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA,
LOUISIANA, MICHIGAN, MINNESOTA,
MONTANA, NEVADA, NEW JERSEY,
NEW MEXICO, NEW YORK, NORTH
CAROLINA, OKLAHOMA, RHODE
ISLAND, TENNESSEE, TEXAS,
VERMONT, AND WASHINGTON; THE
COMMONWEALTHS OF
MASSACHUSETTS AND VIRGINIA;
AND THE DISTRICT OF COLUMBIA,
Plaintiffs,

v.

ALLERGAN, INC., ALLERGAN USA,
INC., ALLERGAN SALES, LLC, FOREST
LABORATORIES HOLDINGS, LTD.,
ADAMAS PHARMA, AND ADAMAS
PHARMACEUTICALS, INC.,
Defendants.

CASE NO. 3:18-cv-3018-JCS

**REPLY IN SUPPORT OF DEFENDANTS'
MOTION TO CERTIFY ORDER FOR
IMMEDIATE APPEAL AND FOR STAY**

Hearing Date: February 5, 2021
Time: 9:30 a.m.
Judge: Hon. Joseph C. Spero

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1 **I. INTRODUCTION**

2 This Court has denied Defendants’ motions to dismiss, holding that the public disclosure bar
 3 of the False Claims Act (“FCA”), 31 U.S.C. § 3730(e)(4), does not apply to Mr. Silbersher’s
 4 complaint. ECF 135. Defendants have since asked the Court to certify this ruling for immediate
 5 appeal. ECF 136. Mr. Silbersher’s opposition brief, ECF 145, casts the motion to certify as little
 6 more than grouching by defendants who disagree with a run-of-the-mill interlocutory order. In doing
 7 so, Mr. Silbersher downplays substantial precedents adopting more expansive readings of the public
 8 disclosure bar, including, among others, *United States ex rel. Silbersher v. Valeant Pharmaceuticals*
 9 *International, Inc.*, 445 F. Supp. 3d 393 (N.D. Cal. 2020) (“*Valeant*”), the only other federal case to
 10 interpret romanette (ii) of the public disclosure bar in light of the FCA’s 2010 amendments. *Valeant*
 11 supports Defendants’ statutory construction here and is on appeal. Mr. Silbersher also downplays
 12 the potential discovery burdens facing the parties—and, importantly, the United States—should this
 13 case advance beyond the pleading stage. Recent public statements from the Department of Justice
 14 (“DOJ”) rebut Mr. Silbersher’s self-serving claim that discovery in declined *qui tam* cases, like this
 15 one, entails only “minor burden on the Government.” ECF 145 at 12. And the opposition brief
 16 exaggerates the potential delay that might accompany interlocutory appeal. Mr. Silbersher estimates
 17 certification would delay this case by “two years or longer,” which, in his view, is far beyond the
 18 date when trial would otherwise occur. *Id.* at 2. But Mr. Silbersher’s imagined trial date—just
 19 eighteen months from now—is not realistic in a case of this complexity and, regardless, the Ninth
 20 Circuit often resolves civil appeals faster than Mr. Silbersher suggests.

21 Because there are substantial grounds for difference of opinion with this Court’s
 22 interpretation of the public disclosure bar and reversal would materially advance the termination of
 23 this litigation, immediate appeal is appropriate under 28 U.S.C. § 1292(b). A stay of proceedings is
 24 also appropriate because “the parties will have incurred any discovery costs inefficiently, or possibly
 25 needlessly, if the Court does not issue a stay and the Ninth Circuit [later] alters the [governing legal]
 26 standard[s].” *United States ex rel. Integra Medical Analytics LLC v. Providence Health & Servs.*,
 27 No. 17-1694, 2019 WL 6973547, at *7 (C.D. Cal. Oct. 8, 2019) (“*Integra II*”). For these reasons
 28 and those discussed below, the Court should grant Defendants’ pending motion.

1 **II. ARGUMENT**

2 **A. The Original Source Question Is No Barrier to Interlocutory Review.**

3 “The trial judge has the discretion to certify a decision for interlocutory review if all of the
4 following statutory elements are met: (1) the order ‘involves a controlling question of law’; (2) there
5 is ‘substantial ground for difference of opinion’; and (3) ‘an immediate appeal from the order may
6 materially advance the termination of the litigation.’” *Integra II*, 2019 WL 6973547, at *2 (quoting
7 28 U.S.C. § 1292(b)).

8 Defendants have identified three controlling legal questions, all of which involve the proper
9 interpretation of romanette (ii) and romanette (iii) of the public disclosure bar. ECF 136 at 6.
10 Mr. Silbersher argues these questions are not “controlling” because “they are not dispositive.”
11 ECF 145 at 6. As he puts it, “[a] resolution in Defendants’ favor might not advance the litigation at
12 all because Relator could still be deemed an original source (a question the Court did not reach)”
13 and “the parties would find themselves two years later litigating that issue.” *Id.* at 6, 2.

14 Mr. Silbersher is mistaken. As a threshold matter, the questions here are dispositive because
15 Mr. Silbersher has no serious claim to the original source mantle. *See Valeant*, 445 F. Supp. 3d
16 at 406–07 (concluding Mr. Silbersher’s original source claim was “wholly conclusory”). His
17 counsel all but conceded this point at oral argument. ECF 116 at 50:6–8, 51:9–10. The Court has
18 also noted that the original source question is a “very hard issue” for Mr. Silbersher. *Id.* at 39:22–
19 40:1. This is unsurprising given that, in the Court’s words, Mr. Silbersher’s complaint “mirrors”
20 documents that were in the public domain years before he filed suit. ECF 135 at 31; *see also*
21 31 U.S.C. § 3730(e)(4)(B)(ii) (an original source must have “knowledge that is independent of and
22 materially adds to” prior public disclosures).

23 Setting all of that aside, legal questions “need not be dispositive of the lawsuit to be
24 controlling” under Section 1292(b). *Federal Trade Commission v. Swish Marketing*, No. 09-3814,
25 2010 WL 1526483, at *1 (N.D. Cal. Apr. 14, 2010); *see also United States v. Woodbury*, 263 F.2d
26 784, 787 (9th Cir. 1959) (“[W]e do not hold that a question brought here on interlocutory appeal
27 must be dispositive of the lawsuit in order to be regarded as controlling.”). On this score, the recent
28 *Integra* case is instructive.

1 The facts of *Integra* are similar to those here. In both cases, non-insider relators filed *qui*
 2 *tam* complaints based on information gleaned from publicly accessible websites. *United States ex*
 3 *rel. Integra Medical Analytics LLC v. Providence Health & Servs.*, No. 17-1694, 2019 WL 3282619,
 4 at *9 (C.D. Cal. July 16, 2019) (“*Integra I*”). The government declined to intervene in both *Integra*
 5 and this case. *Id.* at *3. The *Integra* defendant, like Defendants in the present action, moved to
 6 dismiss the complaint under romanette (iii) of the public disclosure bar. *Id.* at *9. In support, the
 7 *Integra* defendant cited “more than thirty cases”—dated before and after the 2010 FCA
 8 amendments—holding that information generally available on the Internet is “news media” for
 9 purposes of the FCA. *Id.* at *12–13. Judge Gutierrez denied the motion, however, because
 10 “applying the news media provision to anything ever published publicly on the internet is contrary
 11 to the ordinary meaning of the term ‘news media[.]’” *Id.* at 12. In so holding, Judge Gutierrez
 12 acknowledged he was “depart[ing]” from the “general consensus in the federal courts” on the news
 13 media question. *Id.* at *13. He did not address whether the relator was an original source.

14 The defendant moved to certify *Integra I* for interlocutory appeal shortly thereafter. The
 15 relator opposed the motion, raising many of the same arguments Mr. Silbersher advances here. For
 16 example, the *Integra* relator argued the news media question is not “controlling” because of the
 17 outstanding original source issue. *Integra II*, 2019 WL 6973547, at *4. Judge Gutierrez disagreed
 18 because, as noted previously, “[t]he Ninth Circuit has held that appellants do not need to pose a
 19 question of law that will determine who wins on the merits, but instead need only pose a question
 20 that could [avoid] the needless expense and delay of litigating a case.” *Id.* (internal citations
 21 omitted). Judge Gutierrez also found “substantial ground for difference of opinion” with his ruling
 22 in *Integra I* because “numerous cases” have applied “a much broader standard for news media.” *Id.*
 23 The Ninth Circuit granted a subsequent petition for immediate appeal and oral argument is now less
 24 than a month away: February 12, 2021.

25 When Defendants moved to dismiss this complaint under romanette (iii), Mr. Silbersher
 26 cited only one case in opposition—*Integra I*—praising it as “well-reasoned” and stating it
 27 “dictate[d] the same result” in the present action. ECF 80 at 28. This Court agreed, citing Judge
 28 Gutierrez’s “thoughtful analysis.” ECF 135 at 41–43.

Defendants have now moved to certify the Court’s order based explicitly on Judge Gutierrez’s decision in *Integra II*. ECF 136 at 6–8. This time around, Mr. Silbersher ignores *Integra II*, neither distinguishing it from the present action nor explaining why it was wrongly decided. ECF 145 at 6–7. His silence speaks volumes, and he cannot have it both ways. If Judge Gutierrez’s analysis outweighs dozens of federal cases on the news media question, surely his reasoning weighs heavily in Defendants’ favor on the Section 1292(b) question.

B. This Case Presents Exceptional Circumstances Warranting Immediate Appeal.

Mr. Silbersher’s opposition brief emphasizes that the Court has discretion to deny interlocutory review even if Defendants’ motion satisfies every element under Section 1292(b). ECF 145 at 1, 5, 6, and 10. In his words, interlocutory review is an “extraordinary step” that should be reserved for “rare circumstances” presented by “exceptional cases.” *Id.* at 1, 5. And, apparently, Mr. Silbersher sees nothing extraordinary about the present case.

This case is exceptional, however, in at least three respects:

1. It is the *first and only* case to find that romanette (ii) of the public disclosure bar is subject to the same government-party limitation that Congress added to romanette (i), even though Judge Donato in *Valeant* held that romanette (ii) “is not subject to [a] government-party limitation,” 445 F. Supp. 3d at 403, 405–06;
2. It is the *first and only* case to deny a Rule 12(b)(6) motion under the “Federal report” prong of romanette (ii) since the Supreme Court in *Schindler Elevator Corp. v. United States ex rel. Kirk* defined “report” consistent with the “generally broad scope of the FCA’s public disclosure bar,” 131 S. Ct. 1885, 1891 (2011); and
3. It is the *first and only* case to adopt *Integra I*’s novel “news media” test, even though “more than thirty cases” interpret romanette (iii) of the public disclosure bar more broadly, as discussed previously.

These are “rare circumstances” by any measure. And yet, despite the collection of cases interpreting the public disclosure bar more expansively than this Court, Mr. Silbersher maintains that none of them present “substantial grounds for difference of opinion” within the meaning of Section 1292(b) because, as Mr. Silbersher puts it, “[t]he Court’s statutory construction is manifestly correct” and other cases “do not provide a persuasive reason to doubt it.” ECF 145 at 9.

Certification under Section 1292(b) does not depend on whether the order in question was

1 “correct,” but rather on whether “reasonable jurists might disagree on the issue’s resolution.” *Reese*
 2 *v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 688 (9th Cir. 2011). And there is no need to speculate
 3 here; reasonable jurists like Judge Donato, for example, have already disagreed with this Court on
 4 controlling questions of law. These differences of opinion are thus “substantial” and appropriate
 5 for interlocutory review.

6 Mr. Silbersher resists this conclusion as to the *Valeant* case by arguing “it would not warrant
 7 a [Section] 1292(b) appeal simply because another district court reached a different decision in a
 8 broadly similar case.” ECF 145 at 10 (quoting *Tsyn v. Wells Fargo Advisors, LLC*, No. 14-cv-
 9 02552-LB, 2016 WL 1718139, at *6 (N.D. Cal. Apr. 29, 2016)). This dicta from *Tsyn* provides no
 10 support for Mr. Silbersher’s position. *Tsyn* is an overtime-pay case brought under the federal Fair
 11 Labor Standards Act (“FLSA”) and related California laws. *Id.* at *1. In that case, U.S. Magistrate
 12 Judge Laurel Beeler granted partial summary judgment for the defendant on FLSA claims brought
 13 by two plaintiffs while their claims under California law remained pending. *Id.* The plaintiffs, in
 14 turn, filed a Section 1292(b) motion arguing there were “substantial grounds for difference of
 15 opinion” based on a single decision out of the District of Minnesota,¹ in which that court denied
 16 another defendant’s motion for summary judgment concerning FLSA overtime claims brought by
 17 different plaintiffs. *Id.* at *4. In *Tsyn*, the court denied the motion to certify, questioned whether
 18 Section 1292(b) could ever be the “correct vehicle” for interlocutory review of partial summary
 19 judgment decisions, and noted there was nothing “exceptional” about two district courts reaching
 20 different conclusions on Rule 56 motions concerning different parties and different factual records.
 21 *Id.*

22 The present action bears little resemblance to *Tsyn*, which was decided at the summary
 23 judgment stage, not the motion to dismiss stage—a critical distinction in this context. *See, e.g.,*
 24 *Ahrenholz v. Board of Trustees*, 219 F.3d 674, 676 (7th Cir. 2000) (“We think ‘question of law’ as
 25 used in [S]ection 1292(b) has reference to a question of the meaning of a statutory or constitutional
 26 provision, regulation, or common law doctrine rather than to whether the party opposing summary
 27 _____

28 ¹ *In re RBC Dain Rauscher Overtime Litig.*, 703 F. Supp. 2d 910 (D. Minn. 2010).

judgment had raised a genuine issue of material fact.”). Unlike *Tsyn*, the present action involves thorny matters of statutory construction under the public disclosure bar. Such questions are “suited for interlocutory review.” *Integra II*, 2019 WL 6973547, at *2 (holding the proper “definition of ‘news media’ under the FCA” is a controlling question of law for purposes of Section 1292(b)).

Furthermore, the notion that the present action and *Valeant* are merely “broadly similar case[s]” is misguided. ECF 145 at 10. These cases are strikingly similar. Both were filed by the same relator in the same federal courthouse. Both involve the same legal claims and theories of recovery. Both advance similar fraud-on-the-U.S. Patent and Trademark Office (“PTO”) allegations. Both are based on information disclosed publicly during prior patent-related prosecution or *inter partes* review proceedings to which the government was not, in the Court’s view, a party. And both turn on the same dispositive legal question—namely, whether romanette (ii) of the public disclosure bar includes an implied government-party limitation. The only federal jurists to reach this question, Judge Donato and this Court, provided contradictory answers in thoughtful orders analyzing the FCA’s text, history, and purpose. These are “exceptional” circumstances, and they warrant a departure from the general rule disfavoring piecemeal appeals.

C. The Discovery Burdens Here Will Be Far Greater Than Relator Suggests.

Defendants’ moving brief explains why an immediate appeal would materially advance the ultimate termination of this litigation. ECF 136 at 8–9. On this score, “pragmatic considerations” are paramount: “The material advancement prong is met where ‘an interlocutory appeal of an issue may avoid protracted and expensive (but ultimately unnecessary) litigation and the burdens on the litigants and court system that would result from denial of [Section] 1292(b) certification’.” *Integra II*, 2019 WL 6973547, at *4.

Mr. Silbersher argues discovery in this case will be “no more burdensome than in other similar cases,” but rather than compare this case to other declined *qui tam* matters, he instead benchmarks it against two non-FCA cases: *In re Namenda IR Antitrust Litigation*, No. 15-7488 (S.D.N.Y.) (“*Namenda*”), and *In re Restasis Antitrust Litigation*, No. 18-2819 (E.D.N.Y.) (“*Restasis*”). ECF 145 at 11–12. These cases involved massive discovery—millions of pages of documents produced, dozens of fact depositions taken, and numerous expert reports developed and

submitted. In *Restasis*, the parties are still conducting discovery nearly three years after entry of the initial scheduling order.

In his opposition brief, Mr. Silbersher asserts, without evidence, that discovery in the present action will “likely” be less burdensome than in the *Namenda* and *Restasis* cases. ECF 145 at 11–12. Defendants disagree. The time period at issue here (Mr. Silbersher seeks discovery as far back as January 1, 2004) is more expansive than those other cases. So too are the number of patents and pharmaceutical products at issue. Moreover, there was no third-party discovery propounded on federal agencies in *Namenda* and *Restasis*. In this FCA action, however, the parties must seek discovery from the government, as Mr. Silbersher concedes. *See* ECF 145 at 12 (describing certain discovery the parties will need from “the relevant paying agencies.”).

Mr. Silbersher minimizes the government’s potential discovery burdens in this case, but his opposition brief provides an incomplete picture of what government discovery would actually entail. He suggests that the government will be asked to produce nothing more than “drug utilization, purchase, and reimbursement data” that are “already maintained” by the Centers for Medicare and Medicaid Services (“CMS”) and other similar agencies. *Id.*

Those data are only the tip of the iceberg. The parties will also need to obtain relevant documents and testimony concerning the FCA’s “demanding” materiality element. *See Univ. Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003–04 (2016). Misrepresentations and omissions are only actionable under the FCA when they are “material to the Government’s payment decision.” *Id.* at 2002. To that end, “materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation” and, importantly, the government’s continued payment of claims despite “actual knowledge” of alleged FCA violations is “very strong evidence” of immateriality. *Id.* at 2002–04. For these reasons, the United States may need to produce much more than “reimbursement data,” and other parts of the government—like the PTO, the Department of Veterans Affairs, DOJ, and the Food and Drug Administration—may be required to provide relevant information concerning approval of the relevant patents, the government’s investigation into Mr. Silbersher’s *qui tam* allegations, and the reasons for the government’s continued payment of claims for *Namenda XR* and *Namzaric* to the present day.

1 The government has frequently described the burdens shouldered by the United States in
 2 declined *qui tam* cases like this one. They strike a much different tone than Mr. Silbersher's
 3 opposition brief. Here is but one example:

4 Because relators allege nationwide misconduct involving Medicare, Medicaid, and
 5 TRICARE beneficiaries over at least a six-year period, *the government will incur*
 6 *substantial costs in monitoring the litigation and responding to discovery requests.*
 7 For Medicare Part D alone in this period, the drug at issue . . . was prescribed more
 8 than 400,000 times by more than 10,000 different physicians treating more than
 9 15,000 Medicare beneficiaries. The vast scope of the allegations will necessarily
 10 yield substantial, additional investigative and litigation burdens for the United
 11 States. *These burdens include the expense of collecting, reviewing, processing, and*
 12 *producing documents from among multiple federal healthcare programs, as well*
 as voluminous prescription drug event data and patient health information for
 potentially thousands of beneficiaries, which, due to its sensitive nature, may
 require additional (and costly) screening and redaction. Moreover, *the government*
will also have to spend considerable time preparing numerous agency witnesses
for depositions and filing statements of interest relating to a variety of legal
issues[.]

13 Motion to Dismiss, *United States ex rel. SMSPF, LLC v. EMD Serono*, 16-05594, ECF 23 at 15–
 14 16 (E.D. Pa. Dec. 17, 2018) (emphasis added); *see also* Memo. of Law in Support of United States'
 15 Mot. to Dismiss Pursuant to 31 U.S.C. § 3730(c)(2)(A), *United States of America, ex rel. Borzilleri*
 16 *v. AbbVie, Inc., et al.*, No. 15-07881, ECF 275 at 4–5 (S.D.N.Y. Dec. 21, 2018) (stating that “being
 17 a third-party participant in discovery” in a declined *qui tam* action would involve “significant
 18 expenditure of government resources”).

19 These statements show, unmistakably, that continued district court proceedings will be
 20 anything but a “minor burden for the Government,” as Mr. Silbersher has alleged. ECF 145 at 12.
 21 An immediate appeal, however, has the potential to avoid these “protracted and expensive” steps,
 22 *Integra II*, 2019 WL 6973547, at *4, all of which would be wasteful and unnecessary should the
 23 Ninth Circuit reverse this Court’s order denying Defendants’ motion to dismiss. These realities
 24 provide compelling support for Defendants’ pending motion for interlocutory review and for stay.

25 **D. Relator Exaggerates the Potential for Delay.**

26 Mr. Silbersher’s concerns about undue delay, ECF 145 at 11–12, are not well founded. He
 27 claims this case can be “ready for trial” within eighteen months, whereas certification would result
 28 in delay of “two years or longer.” ECF 145 at 2. He is mistaken on both fronts.

As previously discussed, the cases against which Mr. Silbersher benchmarks this action—*Namenda* and *Restasis*—both involved discovery periods longer than what the Relator proposes here. *See* ECF 144 at 13 (reflecting Mr. Silbersher’s proposal that discovery close on December 20, 2021). And the parties in those other cases had to seek multiple extensions of various discovery deadlines during the course of those litigations. The present action involves more complexity and, again, will require extensive third-party discovery from federal agencies that, in Defendants’ experience, requires some time to complete. In short, it is hard to imagine this case will be trial-ready a year and a half from today. Mr. Silbersher’s citations to *Restasis* and *Namenda* only prove the contrary.

On top of this, Mr. Silbersher exaggerates the time required for an immediate appeal. According to the Ninth Circuit’s website, the Court decides most civil appeals “12-20 months from the notice of appeal date.” Office of the Clerk, Frequently Asked Questions, (available at <https://www.ca9.uscourts.gov/content/faq.php>) (updated December 2019). If Mr. Silbersher has concerns about that time frame, he has the option to move to expedite the proceedings under Circuit Rule 27-12. And, even if he foregoes that option, other developments could intervene to shorten interlocutory review of this case. Were the Ninth Circuit to affirm Judge Donato’s ruling in *Valeant*, for example, that would sound the death knell for the present action and, effectively, stop this litigation in its tracks. Reversal of Judge Gutierrez’s ruling in *Integra I* could have the same effect. The *Valeant* and *Integra* cases are already advancing down the appellate path—oral argument in *Integra* is less than a month away—so those appeals have the potential to truncate any interlocutory review process here well before “two years or longer” have elapsed.

E. The Balance of Hardships Weighs Decisively in Favor of a Stay.

Relator’s arguments against a stay also ignore the realities of this case. The Court should grant a stay to avoid burdensome discovery and proceedings that could be entirely unnecessary.

1. Staying the Case Pending Interlocutory Appeal is the Most Efficient Path Forward, and Will Not Prejudice the Relator or the Government.

Mr. Silbersher’s argument against a stay hinges on two speculative assertions: he does not think Defendants will succeed on appeal, and he thinks discovery will be “relatively” costless in the

1 meantime. ECF 145 at 13, 16. Mr. Silbersher is mistaken on both points. In any event, all
 2 Defendants must show at this stage is that there are “serious questions” regarding the merits and the
 3 balance of hardships favors Defendants. There is no real dispute on those issues.

4 Mr. Silbersher asserts that “Defendants do not even attempt to argue they have a strong
 5 likelihood of success on the merits.” ECF 145 at 13. To the contrary, Defendants’ motion
 6 demonstrates that they believe the Court erred in its analysis of key controlling issues and that
 7 Defendants will prevail at the Ninth Circuit. *See generally* ECF 136 at 5–9. Mr. Silbersher has
 8 conceded that every piece of information in his Complaint was in the public domain. *See, e.g.*, ECF
 9 116 at 9:15–25 (counsel for Mr. Silbersher acknowledging that “we would concede that the relevant
 10 information” is in the patent prosecution history on PAIR). His case has survived, thus far, based
 11 on narrow arguments about why—despite his admitted reliance on public sources—his suit
 12 somehow escapes the FCA’s public disclosure bar as amended in 2010. In the order denying
 13 Defendants’ motions to dismiss, the Court had to “grapple” with these issues, ECF 135 at 33,
 14 distinguish a lengthy list of federal cases, including *Schindler Elevator Corp.*, 131 S. Ct. at 1891,
 15 and disagree with Judge Donato’s ruling in *Valeant*. Respectfully, and for each reason detailed
 16 above, Defendants believe they have a very strong likelihood of success.

17 In any event, Mr. Silbersher admits—as he must—that Defendants do not need to show they
 18 are “more likely than not to prevail on [their] appeal,” only that there are “serious questions going
 19 to the merits.” *Senne v. Kansas City Royals Baseball Corp.*, No. 14-00608-JCS, 2017 WL 5973487,
 20 at *4 (N.D. Cal. May 5, 2017) (citing *Leiva-Perez v. Holder*, 640 F.3d 962, 964 (9th Cir. 2011)).
 21 This lower standard is met easily here. In his opposition, Mr. Silbersher acknowledges the need for
 22 “development of law” in this area. ECF 145 at 14. Further, Mr. Silbersher recently told the Ninth
 23 Circuit that similar public disclosure bar questions “rais[e] complex issues of first impression.” Mot.
 24 for Ext. of Time, *Silbersher v. Valeant Pharms. Int’l*, No. 20-16176 (9th Cir. Jan. 8, 2021), Dkt. 52
 25 (requesting 51-day extension). Mr. Silbersher cannot credibly tell the Ninth Circuit that the issues
 26 in *Valeant* are “complex issues of first impression,” and yet tell this Court there are no “serious
 27 questions going to the merits.”

28 Perhaps recognizing the “serious questions” at issue here, Mr. Silbersher’s main argument

1 is that “the balance of hardships” does not favor Defendants. ECF 145 at 13. But this factor weighs
 2 even more decisively in favor of a stay. Mr. Silbersher would not be harmed whatsoever by a stay
 3 because *qui tam* plaintiffs like him have “suffered no injury in fact.” *United States ex rel. Karvelas*
 4 *v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004). And unlike an insider with original
 5 information who blows the whistle, Mr. Silbersher took no personal risks in filing this lawsuit, but
 6 instead seeks to turn copy-and-pasted information from public sources into a private windfall.

7 Mr. Silbersher’s invocation of the government’s purported interests in a “much-needed
 8 financial recovery” and “development of law” is not convincing either. Both the federal and state
 9 governments have declined to intervene in this case, belying the notion that they are deeply
 10 concerned. *See* ECF 7, 15. Regardless, “a delay in recovery of monetary damages alone is generally
 11 not sufficient harm to warrant denial of a stay.” *Prime Healthcare Servs.-Sherman Oaks, LLC v.*
 12 *Price*, No. 16-08098, 2017 WL 8220433, at *4 (C.D. Cal. Apr. 12, 2017) (citing *CMAX, Inc. v. Hall*,
 13 300 F.2d 265, 269 (9th Cir. 1962)); *see also Brown v. Wal-Mart Stores, Inc.*, No. 09-03339, 2012
 14 WL 5818300, at *4 (N.D. Cal. Nov. 15, 2012).

15 On the other side of the ledger, the hardships on Defendants would be significant and
 16 immediate, and they may be unnecessary depending on the outcome at the Ninth Circuit.
 17 Mr. Silbersher argues against certification because “there is no reason to believe discovery here will
 18 be any more burdensome to Defendants than discovery in other complex litigation of its type, with
 19 which Defendants are familiar and to which they are well-equipped to respond.” ECF 145 at 13–
 20 14. Thus, he asks the Court to order immediate “burdensome” discovery simply because Defendants
 21 have undertaken burdensome discovery previously. Lacking any on-point authority, all
 22 Mr. Silbersher can muster is Rule 1’s instruction to secure the “just, speedy, and inexpensive
 23 determination” of cases. What he requests might be “speedy,” but is neither “just” nor
 24 “inexpensive.”

25 Defendants’ experience “in other complex litigation of [this] type” shows precisely why a
 26 stay is appropriate. Mr. Silbersher cites to the *Namenda* and *Restasis* antitrust cases, but, as
 27 explained above, both cases lasted years and cost millions of dollars to litigate. Discovery in this
 28 case would be more complex in key respects because Mr. Silbersher’s theories touch on patent

1 issues, antitrust issues, *and* FCA issues, plus it will require extensive third-party discovery from
 2 various federal agencies, which entails heightened costs and challenges due to applicable *Touhy*
 3 regulations. *See, e.g.*, 45 C.F.R. § 2.3 (U.S. Department of Health and Human Services *Touhy*
 4 regulations, stating that “[n]o employee or former employee of the DHHS may provide testimony
 5 or produce documents in any proceedings to which this part applies concerning information acquired
 6 in the course of performing official duties or because of the person’s official relationship with the
 7 Department unless authorized by the Agency head”). Complexities like these counsel in favor of a
 8 stay until this Court and the Ninth Circuit resolve Defendants’ request for interlocutory review.

9 2. *A Stay Pending Valeant and Integra is Also Appropriate, in the Alternative.*

10 Mr. Silbersher’s argument against a stay pending the *Valeant* and *Integra* appeals relies on
 11 incorrect recitations of law and inaccurate characterizations of those other proceedings. He asserts
 12 that Defendants must show a “pressing need” for a stay because Defendants have requested an
 13 “indefinite stay.” *See* ECF 145 at 15. But the test in the Ninth Circuit is whether “it appears likely
 14 the other proceedings will be concluded *within a reasonable time* in relation to the urgency of the
 15 claims presented to the court.” *Leyva v. Certified Growers of Cal., Ltd.*, 593 F.2d 857, 863–64 (9th
 16 Cir. 1979) (emphasis added); *see also ATSA of Cal., Inc. v. Cont’l Ins. Co.*, 702 F.2d 172, 176 (9th
 17 Cir. 1983) (stay proper if parties proceed with “reasonable diligence”), *amended*, 754 F.2d 1394
 18 (9th Cir. 1985).

19 That standard is met here. *Integra* has proceeded expeditiously, and oral argument is set for
 20 February 12, 2021. *See* Not. of Oral Arg., No. 19-56367, Dkt. 57. *Valeant* is well on its way too—
 21 briefing was to be completed in early February 2021, but will now conclude in April 2021 due to
 22 Mr. Silbersher’s own request for a two-month extension for his reply brief. *See* Order, *Silbersher*
 23 *v. Valeant Pharms. Int’l*, No. 20-16176 (9th Cir. Jan. 12, 2021), Dkt. 55. The Ninth Circuit’s rulings
 24 are nonetheless on the horizon. And there is no “urgency” to the “claims presented to the court”
 25 because, as described above, Mr. Silbersher has suffered no harm, the government has not
 26 intervened, and this case relates to stale allegations and transactions disclosed many years ago.

27 The key question is whether the forthcoming decisions in *Valeant* and *Integra*, individually
 28 or jointly, “may be of valuable assistance to the court in resolving the [claims],” even if they will

1 not “necessarily [be] controlling.” *Levy*, 593 F.2d at 863. As one of Mr. Silbersher’s own
 2 authorities held, the fact that “the pending cases with the appellate courts won’t completely dispose
 3 of every single merits issue in this case ... is also not a reason to deny the stay.” *Phan v.*
 4 *Transamerica Premier Life Ins. Co.*, No. 20-03665, 2020 WL 5576358, at *3 (N.D. Cal. Sept. 17,
 5 2020). The test is not, as Mr. Silbersher suggests, whether other cases will “require the Court to
 6 reverse any of its key conclusions.” ECF 145 at 15.

7 Mr. Silbersher concedes the Ninth Circuit’s decisions in *Valeant* and *Integra* will
 8 “undoubtedly” “address the scope of the public disclosure bar in general,” ECF 145 at 15. That is
 9 sufficient for present purposes, *see Levy*, 593 F.2d at 863, but he undersells the likelihood that the
 10 *Valeant* case, in particular, could control the result of the present action. His opposition brief states
 11 it is “highly unlikely” that *Valeant* and *Integra* “would require the Court to revisit its Order and
 12 revise its rulings” because “neither of those cases deal with the specific questions that Defendants
 13 seek to certify here” including specifically “whether ‘information reported by the PTO on its public
 14 Patent Application Information Retrieval website (‘PAIR’) is a ‘Federal report[.]’” ECF 145 at 2–
 15 3.

16 This is nonsense. Mr. Silbersher briefed this very issue to the Ninth Circuit less than three
 17 months ago. *See Appellant’s Opening Brief, Silbersher v. Valeant Pharms. Int’l*, No. 20-16176 (9th
 18 Cir. Oct. 22, 2020), Dkt. 20 at 59–63 (section entitled “The Patent Prosecution Histories Are Not
 19 Qualifying Public Disclosures” referring to “PAIR” no fewer than fourteen times). The Valeant
 20 defendants also briefed this issue, explaining persuasively why PAIR fits within romanette (ii). *See*
 21 *Defendants-Appellees’ Answering Brief*, No. 20-16176, (9th Cir. Dec. 21, 2020), Dkt. 41 at 46–51
 22 (section entitled “The Public PAIR Database Is a ‘Federal Report’”). An amicus addressed this
 23 question even more recently. *See Brief of Amicus Curie Johnson & Johnson and BTG International*
 24 *Ltd. Supporting Appellees*, No. 20-16176, (9th Cir. Dec. 28, 2020), Dkt. 48 at 14–21 (section
 25 entitled “The Public Disclosure Bar Applies To Documents Filed On PAIR”).

26 Mr. Silbersher may be a party to the *Valeant* appeal, but his characterizations of those
 27 proceedings are inaccurate and the Court should disregard them.

1 **III. CONCLUSION**

2 For the reasons stated in this Reply and Defendants' moving brief, Defendants respectfully
3 ask the Court to certify its Order denying their motions to dismiss for immediate appeal. Defendants
4 further ask the Court to exercise its discretion to stay this case pending the Ninth Circuit's resolution
5 of Defendants' appeal or, alternatively, pending the Ninth Circuit's forthcoming decisions in
6 *Valeant* and *Integra*.

7
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Respectfully submitted,

9 By: /s/ Andrew J. Hoffman II

10 Andrew J. Hoffman II (State Bar No. 259507)
11 Colleen M. McElroy (State Bar No. 307490)
DLA PIPER LLP (US)
2000 Avenue of the Stars
12 Suite 400 North Tower
Los Angeles, CA 90067-4704
13 Telephone: 310.595.3000
Facsimile: 310.595.3300
14 Email: andrew.hoffman@dlapiper.com

15 Matthew Holian (State Bar No. 211728)
DLA PIPER LLP (US)
16 33 Arch Street, 26th Floor
Boston, MA 02110-1447
17 Telephone: 617.406.6000
Facsimile: 617.406.6100
18 Email: matt.holian@dlapiper.com

19 Lisa Tenorio-Kutzkey (State Bar No. 205955)
DLA PIPER LLP (US)
20 555 Mission Street, Suite 2400
San Francisco, CA 94105-2933
21 Telephone: 415.836.2500
Facsimile: 415.836.2501
22 Email: ltk@dlapiper.com

23 *Attorneys for Adamas Defendants*

24 By: /s/ M. Sean Royall

25 M. Sean Royall (admitted *pro hac vice*)
26 Olivia Adendorff (admitted *pro hac vice*)
KIRKLAND & ELLIS LLP
27 1601 Elm Street
Dallas, TX 75201
28 Telephone: 214.972.1770

Facsimile: 214.972.1771
Email: sean.royall@kirkland.com
olivia.adendorff@kirkland.com

John D. W. Partridge (State Bar No. 255570)
GIBSON, DUNN & CRUTCHER LLP
1801 California St., Suite 4200
Denver, CO 80202-2642
Telephone: 303.298.5700
Facsimile: 303.298.5907
Email: jpartridge@gibsondunn.com

Emma M. Strong (State Bar No. 313496)
GIBSON, DUNN & CRUTCHER LLP
1881 Page Mill Road
Palo Alto, CA 94304-1211
Telephone: 650.849.5338
Facsimile: 650.849.5038
Email: estrong@gibsondunn.com

Attorneys for Allergan Defendants